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July 12, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 29852

Re: Docket No. DDN-1256

Dear Sir/Madam:

The National Association of Retired Federal Employees (NARFE) submits the following comments on the notice of public hearing; request for comments published on April 27, 2000 (65 FR 24604). NARFE represents retired Federal employees and their survivors.

On behalf of our 425,000 members (many who are elderly and very dependent on prescriptions prescribed by their physicians), I would like to express our concern that the Food and Drug Administration (FDA) move with great caution in developing any revised approach on the classification of currently physician-prescribed drugs and medications as over-the-counter (OTC) drugs and medications.

We believe that prescription drugs should not be changed to OTC drugs if there is any potentiality for toxicity, lethality, mortality, harmful effects, or similar negative reaction with other drugs, etc. This is necessary to protect all potential users, from the very young to the very old. The FDA process should continue to adamantly reflect these concepts.

The FDA rule that drugs should be granted OTC status only when a consumer can reasonably diagnose a condition (without visiting a doctor), and can understand the labeling (which must be accurate), should also continue to be followed strictly.

Our view is that FDA should adopt the position that drugs and medications whose proper usage requires the supervision of a licensed physician in their administration, adjustment, mixing or change should not be changed to OTC status. This is particularly true, obviously, where misuse of the drugs or medications would create a high potential of harm to the user. Further, many drugs are not conducive to OTC status, because the treatment must be monitored by a physician, and the treatment regime modified accordingly, for the drugs and medications to be used effectively. In the case of a person being treated for hypertension/cardio-vascular disease (H/CVD), the physician prescribes drugs and medications to lower the blood pressure. The

physician provides counseling on life-style changes, recommends an exercise program, gives the patient a diet plan or refers him/her to a dietician, and asks the patient to routinely check his/her blood pressure each day and record the results for the physician's review during the next office visit. The physician advises the patient to call if there is a significant change in the blood pressure readings. Over the course of time, the patient pursues the exercise program, follows the diet plan, and practices clean-living habits. His/her blood pressure goes down, and the drugs and medications portion of the regime is changed, reduced or eliminated. All of these issues factor into the treatment program and effective use of drugs and medications. A review process that grants OTC status to these kinds of drugs and medications -- and terminates the close working relationship with a physician -- can lead to the ineffective use of the drugs and put the users at risk by over-dosage, or inappropriate termination of use of the drugs or medications. Granting these kinds of drugs and medications also removes the other treatment methodologies – diet, exercise program, etc. – from the treatment regime. A process of this kind will not work in the best interests of the general population, the FDA or the pharmaceutical industry, and should be avoided.

Dosage amounts are generally indicated on OTC drugs and medications. An FDA OTC review process must recognize that there are, however, many drugs and medications (now prescribed by physicians) for which a doctor may decide the level of dosage on an individual patient basis, depending on the patients' age, general health, and specific medical conditions. The FDA process must be able to answer this question: How would consumers deal with this dosage issue if these kinds of medications and drugs (for treatment of H/CVD, for example, as discussed above) were deemed OTC?

Drugs that are primarily prescribed for older citizens, or which are prescribed for the treatment of diseases, conditions, and illness that impact older citizens should not routinely be given OTC status. The FDA review process should give credence to the fact that older citizens may be somewhat slower, lack a little less understanding, may be prone to misjudge instructions, and more apt to experiment with dosages on their own than if under the supervision of a physician. OTC sales of drugs that currently must be dispensed under a prescription would lead to experimentation with detrimental consequences under the alleged "growing self-care movement." While a doctor might tell individual "A" to take brand X but not brand Z, three times per day, there would be nothing to keep individual "B" from self-prescribing brands X, Y, and Z. Assuming that individual "A" might follow the doctor's instructions, individual "B" could do whatever he pleased, including stopping all medications at once, notwithstanding labeling precautions to the contrary. Individual "C" could pick up brand X, thinking "my friend "A's" doctor prescribed this for him, so I guess it's okay for me" and be dead three weeks later due the lethality of brand X in concert with other medications he was taking under his individual self-care plan.

The FDA OTC review process must be alert to the fact that people with compulsive or addictive personalities will be at risk if given free rein to use whatever OTC medicines or drugs they decide, on the spur-of-the-moment, is the panacea for whatever issue is disturbing them at the time. People with these kinds of personalities cannot be depended upon to strictly follow protocols of labeling or pharmacological summaries provided with drugs and medications.

Furthermore, OTC sales of medications and drugs would take them out from under the aegis of health insurance coverage for a large segment of the employer-insured population. This would result in additional out-of-pocket costs for millions or enrollees, and family members, hitting the fixed-income elderly the hardest. Even though it may be argued that OTC drugs would be less expensive than the same drugs and medications under the prescription rubric, there are no guarantees that this would be the case. In addition, the reduced OTC cost will still likely greatly exceed the employer-insured cost of prescription drugs and medication, since most employer-sponsored health plans do not cover OTC medications. And, there would be no leveraged purchasing power for large employers to acquire (OTC approved) medications and drugs on a vastly reduced payment schedule since they would be available to anyone OTC.

We note that drugs and medications for the treatment of high cholesterol were previously up for consideration as OTC items. The FDA at that time decided against the OTC label because high cholesterol should be diagnosed and managed by medical professionals. We agree with this assessment. It can be argued, in fact, in the case of cholesterol that depending on the patient, the first treatment might be a dietary change with an exercise program. The more aggressive treatment of using cholesterol-lowering drugs and medications might the first option for some patients, while it would be a second option for others. Giving these kinds of drugs and medications OTC status could very well subvert the medical profession treatment regime.

The same argument can be made for drugs and medications used for the treatment of hypertension/cardiovascular disease and a host of other conditions, including mental illness. The FDA review process should be weighted in favor of disapproval of OTC status for drugs and medications that work best when diagnosed and managed by physicians and other medical professionals.

Many OTC drugs and medications contain warnings such as, "if the condition persists for more than 72 hours, see your physician." An individual who is suffering from diarrhea can take OTC medications for the condition. If the condition continues, people often seek stronger medications or over-dose themselves, rather than go to their doctor or a clinic. Persistent diarrhea can be the symptom of very serious internal disorders, as well as common stomach viruses or food poisoning. Persistent diarrhea that leads to dehydration can be life-threatening for people who are isolated or who live alone. Yet, antidiarrheal treatments are approved, and have been for a long time, as OTC self-care treatments. We have grave concerns that a process that favors approval of physician-prescribed medications and drugs for the OTC category could have dire consequences. People can certainly do themselves great harm by mis-using drugs and medications that have been traditionally prescribed by licensed physicians for the treatment of physical injuries, disorders, and disease, and mental/emotional disease, disorders, and illness. Emphasis needs to continue to be placed on a process that is extremely selective in what drugs and medications are classified as OTC, as discussed in this letter.

In conclusion, I strongly urge the FDA develop a process that errs on the side of excluding drugs and medications from the OTC classification in any case where individual users would be at risk without the supervision or intervention of licensed physicians. This is particularly true of the older segments of our population who often need assistance and guidance in managing their day-today activities. We have received a number of inquiries from our members who object to any change in the current designation of physician-prescribed medication.

Sincerely,

William T. Smith

William T. Smith, Director
Retirement Benefits Service
Department